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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/751,292 | 01/02/2004 | Mark A. Hoffman | CRNC.107055 | 1596 |
| 46169 | 7590 | 12/27/2005 | EXAMINER | |
| SHOOK, HARDY & BACON L.L.P. Intellectual Property Department 2555 GRAND BOULEVARD KANSAS CITY, MO 64108-2613 | | | MILLER, MARINA I | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/751,292 | HOFFMAN ET AL. | |
| | Examiner | Art Unit | |
| | Marina Miller | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/12/04, 9/29/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' submission filed on 1/2/2004 is acknowledged. Claims 1-31 are pending.

Claims 1-31 presently are under examination.

Information Disclosure Statement

Information Disclosure Statements (IDS) filed 4/12/2004 and 9/29/2005 have been considered by the examiner.

Claim Rejections - 35 USC § 101

Non-Statutory Subject Matter

Claims 1-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-31 recite a method for inferring genetic findings for a person comprising receiving a request for genetic findings, determining if the person has actual genetic findings or, alternatively, providing inferred genetic findings. "However, not all processes are statutory under 35 U.S.C. 101." *See* MPEP § 2106. The disclosed method does not recite physical steps to be performed in order to achieve the goal of the method. Steps of receiving and providing information are not limited to physical steps, and all other steps are merely those of data manipulation. The method does not actually transform a set of data, but only recites data (*e.g.*, statistical) manipulations.

When a computer-implemented method does not recite a physical step or an actual transformation of data, it may be statutory when the claimed invention as a whole accomplishes a practical application. "That is, it must produce a useful, concrete and tangible result." *See* MPEP

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§ 2106. In the instant case, the “result” of the method is a determination whether a person has actual genetic findings or providing inferred findings. The claims do not recite tangible expression of the determination or the inferred findings, nor any recitation of an actual (*i.e.*, concrete) result in a form useful to one skilled in the art. Thus, the method does not recite steps of producing something that is concrete, useful, and tangible, and is not statutory.

Lack of Utility

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-31 are rejected under 35 U.S.C. 101 because he claimed invention lacks patentable utility.

Claims 1-31 are directed to a method for inferring genetic findings for a person. The specification discloses on various pages that the invention is useful in “the decision making process,” (p. 3), *e.g.*, determining that a patient does/does not have genetic finding for the RYR1 gene on the basis of testing his family for the trait (p. 19). The result of the method is providing inferred genetic information. The method does not have a substantial utility because one does not know parameters and/or purpose of the inferring. The specification also does not disclose any specific utility for the invention because claims do not recite what genetic findings are being inferred (trait, SNP, mutation, type of chromosomes, chromosome set, *etc.*). In order for the result of the method to be used for inferring genetic findings for a person, one ordinarily skilled in the art must be aware of some correlation between a condition, trait, disease, state of a patient and inferred genetic findings. Absent any disclosure about, for example, the connection of the

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“inferred” genetic findings to a particular disease or trait, the asserted utility is not specific. No such information is recited in the instant claims. Applicant is reminded that a “use” to perform further research is not a utility under 35 U.S.C. 101. For the reason set forth above, the invention lacks a specific and substantial utility, and therefore lacks a patentable utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7, 9, 11, 13, 15-19, 21-23, 25, 27, and 29-31 recite the limitation “genetic findings.” The claims are vague and indefinite because the metes and bounds of the “genetic findings” is not clear, and neither the claims nor the specification defines the limitation. As the intended limitation is not clear, claims 1-31 are indefinite.

Claims 1, 17, and 19 recite “actual” genetic findings. It is not clear whether an “actual” finding is intended to represent the fact of the presence of any genetic information for a patient in a database or the presence of information indicating that the patient has, for example, a mutated (compare to normal) allele, gene, *etc.* As the intended limitation is not clear, claims 1-31 are indefinite.

Claims 1, 6, 9, 11, 13, 16, 17, 22, 25, 27, 29, and 31 recite “inferred genetic findings.” The limitation is not clear because a source from which genetic findings are “inferred” and/or

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criteria of “inferring” is not clear and neither the claims nor the specification define “inferring.”

As the intended limitation is not clear, claims 1-31 are indefinite.

Claims 6 and 22 recite “an inferred genetic finding.” Claims 6 and 22 depend from claims 1, 4, and 5 and 17, 20, and 21, respectively, wherein claims 1 and 17 already recite “inferred genetic findings.” It is not clear whether “an inferred genetic finding” of claims 6 and 22 is intended to be different from the genetic findings of claims 1 and 17. As the intended limitation is not clear, claims 6-7 and 22-23 are indefinite.

Claims 1 and 17 recite the limitation “if the person does not have actual genetic information, automatically providing inferred genetic information.” The claims are vague and indefinite because it is not clear whether “providing inferred genetic findings” is intended to be an active, positive method step. As the intended limitation is not clear, claims 1-31 are indefinite.

Claims 1 and 17 recite in the preamble “[a] method ... for inferring genetic findings.” However, the method does not recite an actual step of “inferring,” and comprises a step of either determining “actual genetic findings,” or in alternative “providing” already inferred genetic findings.” Thus, the intended relationship between the preamble and the method steps is unclear and, therefore, claims 1-31 are indefinite.

Claim 2 recites “the method of claim 1 wherein the step of determining if the person has stored genetic findings.” There is insufficient antecedent basis for this limitation in the claim. Claim 2 depends from claim 1, wherein claim 1 does not recite a step of determining if the person has stored genetic findings, but comprises a step of determining if the person has actual genetic findings. As the intended limitation is not clear, claims 1-16 are indefinite.

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Claims 2 and 18 recite “the electronic medical record.” There is insufficient antecedent basis for this limitation in the claim. Claims 2 and 17 depend from claims 1 and 17, respectively, wherein claims 1 and 17 do not recite “an electronic medical record.” As the intended limitation is not clear, claims 1-31 are indefinite.

Claim 3 recites “a decision support rule.” It is not clear what limitation is intended and neither claims nor the specification define “a decision support rule.” As the intended limitation is not clear, claim 3 is indefinite.

Claims 4, 15, 20, and 30 recite the limitation “the traversal pattern.” There is insufficient antecedent basis for this limitation in the claim. The claims depend from claims 1, 12, 17, and 28, respectively, which do not recite a traversal pattern. Further, the limitation is not clear and neither the claims nor the specification defines a “traversal pattern.” As the intended limitation is not clear, claims 1-31 are indefinite.

Claims 4-7, 15-16, 20-23, and 30-31 recite “the genetic findings.” It is not clear what limitation is intended because independent claims from which claims 4-7, 15-16, 20-23, and 30-31 depend recite multiple genetic findings, *e.g.*, “actual,” “stored,” and “inferred.” As the intended limitation is not clear, claims 4-7, 15-16, 20-23, and 30-31 are indefinite.

Claim 14 recites “the inferred results.” There is insufficient antecedent basis for this limitation in the claim. Claim 14 depends from claim 1 which does not recite an inferred result, but recites “inferred genetic findings.” As the intended limitation is not clear, claim 14 is indefinite.

Claims 16 and 31 recite “the genetic marker information.” There is insufficient antecedent basis for this limitation in the claim. Claims 16 and 31 depend from claims 15 and 31,

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respectively, which recite “genetic markers,” but do not recite “genetic marker information.”

Further, claims 15 and 30 recite multiple genetic markers. However, claims 16 and 31 recite information of a single genetic marker and it is not clear which genetic marker information is utilized in claims 16 and 31. As the intended limitation is not clear, claims 16 and 31 are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Morand, US 2002/0046054.

Morand discloses a computer-implemented method and a system for identifying genetic information of an individual by using a database [0016]. Morand discloses receiving a request for genetic information (*i.e.*, “findings”) for a person [0036] and [0062], in response to the request, determining if the person has actual or specific genetic information or alternatively, providing inferred genetic information for the person [0062] and [0074]-[0078], fig. 1, 2. Thus, Morand anticipates instant claims 1 and 17. Morand discloses storing genetic findings and searching electronic medical records for a person [0074-0078], thus anticipating claims 2 and 18. Morand discloses initiating a request by a decision support rule (*i.e.*, query protocols) [0049] and

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[0077], thus anticipating claim 3. Morand discloses obtaining a result in response to query (traversal pattern for genetic findings) [0061], thus anticipating claims 4 and 20. Morand discloses using family history data for obtaining genetic findings (*see* claim 7 and [0051]), thus anticipating instant claims 5-7 and 21-23. Morand discloses obtaining cytogenetic and demographic observations (*see* table 1), thus anticipating claims 8-11 and 24-27. Morand discloses using genetic markers associated with genetic diseases or a stage of a disease [0032], thus anticipating claims 12-13, 15-16, and 28-31. Morand discloses the communication of an inferred result to a user [0029], [0043], thus anticipating claim 14. Morand discloses a request for actual genetic findings from a user [0043], thus anticipating claim 19.

Claims 1-11, 14, and 17-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Girn, US 2003/013727.

Girn discloses a computer-based method and a computer system of screening for a genetic trait based on a family history (abstract). Girn discloses receiving a request for genetic findings for a person, in response to the request, determining if the person has actual genetic information or alternatively, or providing inferred genetic information for the person (*see* claim 11, [0049]-[0050], [0053], [0077]-[0081]). Thus, Girn anticipates claims 1 and 17. Girn discloses storing genetic information and searching an electronic database (*see* fig. 1), thus anticipating claims 2 and 18. Girn discloses initiating a request by a decision support rule, [0080] (*e.g.*, a user initiates data entry, enters a particular genetically linked illness, and edits his family history data so that a reference database is queried according to a user's query), thus anticipating claim 3. Girn discloses obtaining a traversal pattern (risk analysis) for genetic findings [0077]-[0079],

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thus anticipating claims 4 and 20. Girn discloses inquiring whether family members have a genetic finding and utilizing family history data for obtaining genetic findings [0053], [0079]-[0081], [0083], thus anticipating instant claims 5-7 and 21-23. Girn discloses obtaining cytogenetic and demographic observations [0089], [0092], [0133]-[0134], [0031], thus anticipating claims 8-11 and 24-27. Girn discloses the communication of an inferred result to a user and a request for actual genetic findings from a user (fig. 1), thus anticipating claims 14 and 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-13, 15-16, and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girn, US 2003/013727, as applied to claims 1-11, 14, and 17-27 above, and further in view of Pikar, US 2003/0108938.

Girn teaches the method of claims 1-11, 14, and 17-27, as set forth above.

Girn does not teach using genetic markers.

Pikar discloses a method of analyzing genotypes and clinical phenotypes for selecting individuals for conducting clinical trials. Pikar discloses creating a genomic database for individuals [0031] and selecting particular individuals based on pre-determined criteria. Pikar

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discloses using genetic marker information pertaining to a specific clinical trial (e.g., specific disease or trait) [0062].

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Girm to use genetic marker information, such as taught by Pickard, where the motivation would have been to monitor the composition of the population, as taught by Pickard [0062].

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
10/27/05

Marina Miller
Examiner
Art unit 1631